REMARKS

Claim Rejections – 35 USC 103

Claims 1-4, 6 and 8-17 are rejected under 35 USC §103(a) as being unpatentable over McMichael et al. (WO 98/56919 – IDS filed on 4-11-08) and Sallberg et al. (US patent application publication US 2002/0165172).

The newly amended claim 1 is drawn to a method to immunize a subject against malarial disease comprising: a) administering to the subject a priming immunization preparation comprising one or more alphavirus replicon expressing a gene encoding a malarial antigen or combination of malarial antigens; and b) subsequently administering to the subject a boosting immunization preparation comprising the malarial antigen or combination of malarial antigens, wherein said preparation is a recombinant non-alphavirus viral expression system encoding the malarial antigen; wherein the malarial antigen is selected from the group consisting of: PfEXP1, PfSSP2, PfLSA-1, PfLSA-3, PfMSP-1, PfAMA-1, PfEBA-175, PfMSP-3, PfMSP-4, PfMSP-5, PfRAP-1, and PfRAP-2.

Claim 17 is directed to a method to immunize against malarial disease, comprising priming with a VEE replicon particles expressing a gene encoding a malarial antigen or immunogenic fragment thereof, and boosting with an immunization preparation comprising poxvirus encoding the malarial antigen, wherein the malarial antigen is selected from the group consisting of: PfEXP1, PfSSP2, PfLSA-1, PfLSA-3, PfMSP-1, PfAMA-1, PfEBA-175, PfMSP-3, PfMSP-4, PfMSP-5, PfRAP-1, and PfRAP-2.

Response

McMichael et al. disclose methods of inducing CD8 T cell immune response to malarial antigens comprising the administration of a priming composition of a nucleic acid (DNA or RNA), which may be either packaged or in free form; and a boosting composition comprises a non-replicating or replication-impaired pox virus vector, which may be a Ty-VLP or a recombinant adenovirus. McMichael et al. further disclose that MVA may be used in both priming or boosting composition and other viral vectors, such as herpes virus can be used in the priming composition. However, McMichael, as the examiner noted, do not explicitly teach the use of alphavirus generally, or the use of VEE virus specifically. McMichael et al also fail to teach the specific malarial antigens encoded by said alphavirus replicon and used in the boosting immunization preparation.

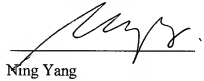
Sallberg et al disclose a method for treating intracellular infections within warm-blooded animals, comprising: (a) administering to a warm-blooded animal a vector construct, which directs the expression of at least one immunogenic portion of an antigen derived from an intracellular pathogen; and (b) administering to said warm-blooded animal a protein which comprises said immunogenic portion of said antigen, such that an immune response is generated. Sallberg further discloses that the method may be used to treat malaria and said vector construct may be carried by an alphavirus. However, Sallberg also fail to teach the malarial antigens other than PfCSP.

Claim 1 and claim 17 are currently amended to delete PfCSP from the list of malarial antigens. As amended, the combined prior art references do not teach the specific malarial antigens or combination of antigens currently claimed in claims 1 and 17. Because these antigens are critical components of the immunization preparation of

the present invention, and are responsible for the preparation's immunogenecity against malaria, an immunization method without clearly defined malarial antigens will not anticipates the current invention. Applicants respectfully request the rejections against newly amended claims 1 and 17 and its dependent claims be reconsidered and withdrawn. Claims 3 and 8 are amended to remove the markush claim language since there is only one species is election.

The commissioner is authorized to deduct any fees and credit any overpayments using USPTO deposit account No.140,595

Respectfully submitted,



Ning Yang
Registration No. 55,750
Customer No. 22245
Phone: 301 319-9433
Fax: 301 319-7432

Date: 11 Sept. 2009

cc: Kimpel Janice, AlphaVax Inc.